



**Comments of the Association of Public Health Laboratories regarding the  
Interim Final Rule “Possession, Use and Transfer of Select Agents and Toxins,”  
42 CFR Part 73, and Part 1003  
Federal Register, December 13, 2002, pages 76886-76905**

**Comments submitted February 11, 2003**

The Association of Public Health Laboratories is a national, non-profit association dedicated to working with its members to actively promote the interests of public health laboratories. By promoting strong programs and public policy, APHL works to ensure that public health laboratories have the resources and infrastructure they need to protect the health of U.S. residents and to prevent and control disease globally. APHL members include state and local public health laboratorians and others committed to bolstering national security through a sound and competent laboratory infrastructure. We appreciate the opportunity to comment on the interim final rule governing the possession and transfer of select biological agents and toxins.

APHL has supported a rigorous process to assure that select agents used in laboratories are not diverted to individuals with intent to harm Americans. **We are in general agreement with the intent and the provisions of the interim final rule**, and comment on specific sections below. We must note, however, that the administrative and paperwork requirements for compliance are substantial. We appreciate the efforts of Select Agent Program staff in outreach and education to facilitate compliance, but **we request that every effort be made to minimize administrative burdens in the final rule.**

**Regarding Sec 73.7, Registration:**

APHL notes that this program will create a federal database of entities nationwide that are in possession of various listed agents.

APHL supports a core national security activity, the Laboratory Response Network for Bioterrorism (LRN). The LRN is comprised of more than 100 federal, state and local laboratories using standardized protocols and reagents in a secure network, supported by the Centers for Disease Control and Prevention (CDC) to confirm findings of suspected agents of bioterrorism. The fifty state public health laboratories form the backbone of this network, and were responsible for analysis of 69% of more than one million anthrax samples handled in the fall of 2001.

State public health laboratories worked as indispensable partners in responding to the anthrax attacks, and stand ready to serve again as needed. State public health laboratory

directors have asked if information about registered entities in their states can be made available. APHL has been told that the current secure nature of the select agent database precludes CDC from sharing this information. However, this information could be used by state emergency management officials to better plan the protection of these vulnerable locations.

**APHL requests that consideration be given to sharing state-specific registrant lists in this federal database with appropriate officials in specific states.** Beyond its use in emergency planning, such information could be used by state public health laboratory directors to conduct training and other outreach for clinical laboratories, which serve as screening sites for the early detection of illness due to bioterrorism agents. Indeed, the obligation of state public health laboratory directors to provide meaningful outreach to these national security partners was laid out as Critical Benchmark #10 in the announcement of Cooperative Agreement Awards for Focus Area C – Laboratory Capacity – Biological Agents, the mechanism for delivering emergency supplemental funds to state public health laboratories. The Cooperative Agreement notice states that each applicant must develop “a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B/C Laboratory Response Network laboratories to ensure that Level A laboratories maintain core capability to: (a) perform rule-out testing on critical BT agents; (b) safely package and handle specimens; and (c) refer to higher level laboratories for further testing.”<sup>1</sup>

#### **Regarding Sec. 73.6(a) Exemption Regarding Diagnosis, Verification, or Proficiency Testing:**

Paragraph (a) of Sec. 73.6 states that an entity is exempt from registration if the only activities conducted by the entity involve select agents or toxins contained in specimens or isolates from the specimens presented for diagnosis, verification, or proficiency testing. It states that identification of certain agents requires immediate notification of the Secretary of Health and Human Services, and that the entity must report the finding of these and other agents as required under Federal, State, or local law, to appropriate authorities. Such entities are then required to destroy these agents within seven calendar days if used for diagnosis or verification, or within 90 calendar days if used for proficiency testing, unless directed otherwise by the Federal Bureau of Investigation.

There may be circumstances in which a state public health laboratory director would want such specimens or isolates preserved to support epidemiologic investigations in the state. This may be the case when nefarious activity is not suspected, such as isolated cases of *Yersinia pestis* infection in the Southwest, but for which state-based infection control activities must proceed. State reporting requirements vary, and in any case are inconsistently adhered to. The interim final rule essentially says that an entity must notify the Secretary within seven calendar days if certain agents are found, and that these can be destroyed upon consultation with the Secretary and the FBI. **APHL urges that the final rule require the inclusion of the state public health laboratory director or other appropriate contact such as the state health officer in this consultation. We also suggest that depending on the nature of these**

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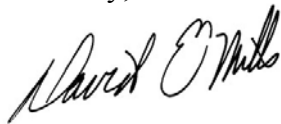
<sup>1</sup> CDC Announcement #99051, Emergency Supplemental, February 15, 2002, available at <http://www.bt.cdc.gov/planning/CoopAgreementAward/CDC5BTATTACHMENT-C-MASTER-2-19-2002-200pm.asp>

**situations, seven calendar days may not provide sufficient time for all necessary communications to ensue, and that this timeframe should be expanded.**

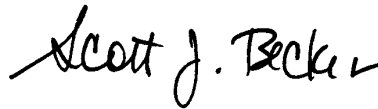
**Conclusion:**

APHL appreciates the opportunity to comment on the interim final rule governing the possession and transfer of select biological agents and toxins. For further information or to clarify our comments, please contact Dr. Sarah Lister, Director of Public Health Preparedness, 202-822-5227 x207, [slister@aphl.org](mailto:slister@aphl.org), or Chris Mangal, Manager for Emergency Preparedness and Response, 202-822-5227 x244, [cmangal@aphl.org](mailto:cmangal@aphl.org).

Sincerely,



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